DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

Volcano Corporation
Neeta Sharma
Director, Regulatory Affairs
3721 Valley Centre Dr, Suite 500
San Diego, California 92130

Re: K150441
Trade/Device Name: Volcano iFR Modality, iFR Scout Feature
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO
Dated: February 19, 2015
Received: February 20, 2015

Dear Neeta Sharma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Shawn W. Forrest -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known)

Device Name Volcano iFR® Modality

Indication for Use

The iFR® Modality of the s5/s5i/CORE and CORE Mobile Precision Guided Therapy System is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. The iFR® Modality is intended to be used in conjunction with currently marketed Volcano pressure wires.

Prescription Use ____X____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) SUMMARY

SPONSOR:

Volcano Corporation
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CONTACT/SUBMITTER:

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DATE PREPARED: February 19, 2015

DEVICE: Volcano iFR ® Modality

TRADE NAME: Volcano iFR ® Scout™

COMMON NAME: Ultrasonic Pulsed Echo Imaging System

CLASSIFICATION: 21 CFR Part 892.1560
IYO: System, Imaging, Pulsed Echo, Ultrasonic
Class II Device

PREDICATE DEVICE: Volcano iFR® Modality (K133323)

DEVICE DESCRIPTION: New software feature have been added to the iFR Modality Live iFR and iFR Pullback that allow the assessment of a lesion (single cycle iFR measurement) or vessel (pullback measurement) in a resting condition without the requirement of a hyperemic agent. Both features, collectively referred to as the iFR® Scout allow the user to assess a length of vessel by placing the pressure sensor distally, record/measure, and pull the sensor back through the vessel to a stopping point. This generates a map of the wave-free pressure gradient iFR values along the vessel and a distal iFR value that represents the condition of the vessel at the most distal point of the recording.

INTENDED USE: The iFR® Modality of the s5/sSiCORE/CORE Mobile Precision Guided Therapy System is indicated in all blood vessels, including coronary and peripheral arteries, to

measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. The iFR® Modality is intended to be used in conjunction with currently marketed Volcano pressure wires.

COMPARISON OF CHARACTERISTICS:

The iFR® Scout™ feature will enable iFR measurements to be recorded along a length of vessel. This feature will provide iFR data that can be used to determine the degree of disease in the vessel as well as the relative significance of individual lesions or diseased segments along the length of the vessel. The results of the iFR pullback measurement are displayed as a map of the pressure gradient and an adjacent display of the pressure waveforms and ECG, similar to the current spot measurement display.

PERFORMANCE DATA:

Performance testing completed for a determination of substantial equivalence included the following:

- Software Verification
- Software Validation

The results of the performance data demonstrate equivalence to the predicate device.